

DATE OUT: 21/JUN/00

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use [], End Use Product [x]
BARCODE No.: D266547 EPA RECEIVED DATE: 06/07/00 Reg./File Symbol No.: 211-36
PRODUCT NAME: Tri-Cen Germicidal Detergent MRID number: 451297-01
COMPANY NAME: Central Solutions, Inc. Action Code: 674

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Product Chemistry Team
PRB/SRRD (7508C) 6/7/00

TO: Barbara Briscoe, CRM
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INTRODUCTION:

The registrant submitted a CSF for the basic formulation dated 04/24/00, a product label (stamped EPA accepted 05/19/99), and product chemistry data (MRID number 451297-01). The registrant is requesting FIFRA Section 4 reregistration of the product, Tri-Cen Germicidal Detergent, EPA Reg. No. 211-36.

A Reregistration Eligibility Decision (RED), Case number 2045, was issued in November 15, 1996 for the Technical Grade Active Ingredient (TGAI), Ortho-benzyl-para-chlorophenol (and its sodium and potassium salts). The generic data base supporting the reregistration of OBPC has been reviewed and found to be substantially complete. However, product chemistry data on the inorganic salts are still required.

FINDINGS:

1. The information concerning the analytical method for *o*-benzyl-*p*-chlorophenol, *o*-phenyl-phenol and *p*-*t*-amylphenol is adequate and satisfies the data requirements under Guideline 830-1800, Enforcement Analytical Method.
2. The CSF, a basic formulation, dated 04/24/00, will need to be revised as follows:
 - a. The nominal concentrations of the active ingredients presented on the CSF do not agree with that on the label. According to the EPA REFs files, the strength of the two OBPC technical is [REDACTED] each (the registrant has not reported the purities of all the technical sources), the OPP technicals are [REDACTED] and the PTAP is [REDACTED]. When the purity of these technicals are multiplied by the reported percentages by weight of each active ingredient, the resulting nominal concentrations do not match the label claim nominal concentrations. Thus for OBPC, [REDACTED] For OPP, [REDACTED] when multiplied by [REDACTED] respectively. For PTAP, [REDACTED]. These values do not agree with the label nominal concentrations. The registrant must make the necessary corrections because the label must agree with the CSF.

Product ingredient source information may be entitled to confidential treatment

- b. In addition, to have consistency with the label, the sodium salt forms of OBPC, OPP and PTAP must be indicated on the CSF. The nominal concentrations should be based on the salt forms.
- c. Once the sodium salts of each active ingredient are listed, then the upper and lower certified limits should be corrected based on the nominal concentrations of each (see reviewer's notes on the CSF for guidance).

Other information presented on the CSF are acceptable. The certified limits on all the inert ingredients are acceptable per 40 CFR 158.175(b)(2). All ingredients presented on the CSF are cleared for use in pesticide formulations.

- 3a. The Ingredient statement on the label is acceptable and is in compliance with the requirements of 40 CFR 156.10(g) and PR Notice 91-2.
- 3b. The Flammability data on this product (i.e., 115°F) triggers a Physical or Chemical Hazard warning on the label. The statement "Combustible. Do not use or store the product near heat or open flame.", must be placed under the Physical or Chemical Hazard subheading. This revision is to be addressed as part of the Label Assessment Team review.
- 3c. The Storage and Disposal statements comply with the requirements of 40 CFR 156.10(I)92)(ix) and PR Notice 83-3.

CONCLUSIONS:

After submission of a revised CSF (Findings 2a, b, and c), the registrant will satisfy product chemistry data requirements for the reregistration of the end-use product, **Tri-Cen Germicidal Detergent**, EPA Reg. No. 211-36.

NOTE TO CRM/PM:

The label-related issue noted in Finding 3b should be addressed as part of the Label Assessment and Acute Toxicity reviews.

REVIEW OF PRODUCT CHEMISTRY DATA:

PRODUCT NAME: Tri-Cen Germicidal Detergent

EPA Reg. No: 211-36

Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).

830-1550 Product Identity and Composition

This product is produced by a non-integrated formulation process using EPA-registered products, OBPC [REDACTED] with [REDACTED] as the alternate source; OPP [REDACTED] with [REDACTED] as the alternate source; and para-tertiary-amylphenol, [REDACTED] This end-use product has a label claim nominal concentrations of 4.40% sodium ortho-benzyl-para-chlorophenate, 2.82% sodium ortho-phenylphenate, and 2.49% sodium para-tertiary-amylphenate, with 90.29% inert ingredients.

830-1600 Description of Materials Used to Produce the Product

Refer to Confidential Appendix A.

830-1620 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A.

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method:

O-phenyl-phenol, o-benzyl-p-chlorophenol and p-tertiary-amylphenol are analyzed by "Analysis Method for the Determination of p-t-amylphenol, o-phenylphenol, and o-benzyl-p-chlorophenol in EPA Reg. No. 211-36, RDM-60A by Gas Chromatography" (Brandywine Research Laboratory, Inc.; Method 6891-2).

Information on method validation ("Method Validation and System Suitability; Analysis of EPA Reg. No. 211-36 by Gas Chromatography", Brandywine Research Laboratory, Inc.; Method 6891-2) indicates that the method is adequate in quantifying the active ingredients in this product.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190):MRID Nos.: 451297-01

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES																
-6302 Color	Clear amber liquid, may darken with age.																
-6303 Physical State	Liquid.																
-6304 Odor	Mild phenolic/lavender.																
-6314 Oxidation/Reduction: Chemical Incompatibility	“This product is not known to have any oxidizing or reducing potential.”																
-6315 Flammability/Flame Extension	115°F (SETA)																
-6316 Explodability	“Not potentially explosive.”																
-6317 Storage Stability of the Product	<table><tr><td></td><td>Initial</td><td>After 12 months</td><td>After 24 months</td></tr><tr><td>% OBPC -</td><td>4.1</td><td>4.1</td><td>4.1</td></tr><tr><td>% OPP -</td><td>2.6</td><td>2.6</td><td>2.6</td></tr><tr><td>% PTAP -</td><td>2.3</td><td>2.2</td><td>2.3</td></tr></table> <p>Except for some color change, the product did not show any other significant changes when stored over a period of two years. “It is well documented in the phenolic manufacturing industry that phenolics do undergo color change during the aging process, and that this normal occurrence does not affect product efficacy. The pH, specific gravity and active levels indicate consistent stability.”</p>		Initial	After 12 months	After 24 months	% OBPC -	4.1	4.1	4.1	% OPP -	2.6	2.6	2.6	% PTAP -	2.3	2.2	2.3
	Initial	After 12 months	After 24 months														
% OBPC -	4.1	4.1	4.1														
% OPP -	2.6	2.6	2.6														
% PTAP -	2.3	2.2	2.3														
-6319 Miscibility	“Completely”																
-6320 Corrosion Characteristics	“This product is non-corrosive to stainless and carbon steel.”																
-6321 Dielectric Breakdown Voltage	“This product is not intended nor labeled for use in or around electrical equipments.”																
-7000 pH	Concentrate - 12.00 to 12.50 Diluted 1:256 - 10.00 to 11.00																
-7100 Viscosity	5 cps, Brookfield spindle #1, 30 rpm, 25°C																
-7300 Density/Relative Density/ Bulk Density	Specific gravity @ 25°C: 1.088 ± 1.096																

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product

The materials used in the formulation of this product are listed on the CSF, a basic formulation dated 04/24/00.

830-1650 Description of Manufacturing Process830-1670 Discussion of Formation of Impurities830-1700 Preliminary Analysis

Not required for non-integrated products.

830-1750 Certified Limits

See Findings 2a, b, and c, and the CSF.

Manufacturing process information may be entitled to confidential treatment